

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

**IN RE: VALSARTAN
PRODUCTS LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Judge

Honorable Joel Schneider,
Magistrate Judge

**PLAINTIFFS' SECOND AMENDED SET OF REQUESTS FOR
PRODUCTION OF DOCUMENTS TO RETAIL PHARMACY
DEFENDANTS**

TO ALL DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1, and in accordance with the Court's rulings at oral argument on December 11, 2019 and December 18, 2019, and in the Order filed on December 13, 2019, as well as the Court's Order on macro discovery issues filed on November 25, 2019, Plaintiffs propound the following second amended set of requests upon each Retail Pharmacy Defendant.¹ These requests are without prejudice to Plaintiffs' rights to serve other requests consistent with Rules 26 and 34.

¹ Each request is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; the November 25, 2019 Order on macro discovery issues pertaining to the Manufacturing Defendants (Dkt. 303); the parties' representations as reflected in the record of the December 11, 2019 discovery hearing; and the Court's oral and/or written rulings following the December 11, 2019 discovery hearing, the January 15, 2020 discovery hearing, the January 28, 2020 discovery conference, and the February 13, 2020 discovery conference.

DEFINITIONS:

“Active Pharmaceutical Ingredient” (“API”) is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance. 21 C.F.R. § 207.1; see also 21 C.F.R. § 314.3.

“API Manufacturer” is defined as any entity identified as a Defendant in Plaintiffs’ Master Personal Injury Complaint that manufactures the active pharmaceutical ingredient (API) for valsartan.

“Finished Dose Manufacturer” includes any entity identified as a Defendant in Plaintiffs’ Master Complaints that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term “finished dose manufacturer” also includes entities who hold ANDAs.

“Manufacturer Defendants” includes API Manufacturers and Finished Dose Manufacturers including any subsidiaries or affiliated entities.

“Communication(s)” means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

“Documents” includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term “Document” includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form). Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database. For purposes of these discovery requests, “Documents” shall refer only to centrally stored, non-custodial data maintained by the retailer pharmacy in the ordinary course of business and available

via reasonable search of available records, and shall not refer to documents or data maintained solely by individual stores or pharmacies, or to emails or custodial data held by individual employees of the Retail Pharmacy Defendants.

Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is January 1, 2012 through the December 31, 2019.

“Regulatory and Regulatory Authority” refers to United States Food & Drug Administration.

“Retail Pharmacy Defendants” refers to any and all entities listed by name as “Retail Pharmacy Defendants” in Plaintiffs’ June 17, 2019 Master Personal Injury Complaint (Dkt. No. 121), including any agents, employees, or predecessor entities.

“TPP” refers to Third Party Payors, including health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payers, and any other health benefit provider in the United States of America and its territories.

“Valsartan” or “VCDs” means any drug with valsartan as an active ingredient. For purposes of these Requests, “Valsartan” or “VCDs” is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs’ Master Personal Injury Complaint.

“Recalled Valsartan” or “Recalled VCDs” means any drug with valsartan as an active ingredient, as well as all finished drug formulations of valsartan, including any valsartan containing drug, that was subject to a voluntary or mandatory recall, to the extent identifiable from Documents kept by the Retail Pharmacy Defendant(s) in the ordinary course of business.

“You,” “your” or “defendant” shall be used interchangeably and refers to the parties to which these requests are directed.

“Drug Supply Chain Security Act” refers to Pub. L. 113-54 and regulations promulgated thereunder.

“Wholesaler Defendants” refers to Amerisource Bergen Corporation, Cardinal Health, Inc., or McKesson Corporation, as identified in Plaintiffs’ June 17, 2019 Master Complaint (Dkt. No. 121), including any agents, employees, or predecessor entities, to the extent known to the Retail Pharmacy Defendants.

INSTRUCTIONS:

Non-privileged information: These Requests seek only information that is not privileged or otherwise protected from disclosure by applicable protection, including but not limited to work product protection or other requirements imposed or protections afforded by applicable law or regulation. This does not relieve any responding Defendant from serving a privilege log consistent with the Federal Rules of Civil Procedure.

DOCUMENTS TO BE PRODUCED:

I. SOURCING (UPSTREAM)

1. Documents sufficient to identify the VCDs purchased by you during the relevant time period, including quantity/units, dates of purchase, price paid, NDC, supplier, expiration date, batch and lot number.
2. Documents sufficient to identify as exemplar the ordinary-course transactional documents accompanying VCDs purchased by you (e.g., invoices, bills of lading, packing slips, etc.).

II. SALES (DOWNSTREAM)

3. Documents sufficient to identify as exemplar the type of manufacturer-included packaging or labeling information for VCDs dispensed by you.
4. Documents sufficient to identify your sale of VCDs to consumers, in either of the forms identified in Requests 4(a) and 4(b), below. You need only produce this information in one of these formats.
 - a) Documents sufficient to identify the quantities/units and number of purchasers of VCDs dispensed by you, by month, state/territory, expiration date, and NDC, as well as by lot number if available.
 - b) Documents sufficient to identify when and to whom you dispensed VCDs, including quantity/units, NDC, expiration date, batch, and lot number.
5. The gross and net price paid by consumers and TPPs for VCDs dispensed by you identified in Request No. 4, for the time period of [SAMPLE DATE RANGE], to be produced in an anonymized manner. You also may redact protected patient information to address any privacy or HIPAA concerns raised by the production of this data, as appropriate.

III. WARRANTIES/STATEMENTS (UPSTREAM)

6. Documents sufficient to show your final written policies or procedures for the types of documents or other information to be provided by a prospective supplier and/or manufacturer of VCDs purchased by you.
7. Documents sufficient to show the information provided to you by the Manufacturer Defendants or Wholesaler Defendants from which you actually purchased VCDs.

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IV. WARRANTIES/STATEMENTS (DOWNSTREAM)

8. Documents sufficient to show your final written policies for the types of documents or other information and materials to be provided by you (whether such materials were created by you or not) when you dispensed VCDs to consumers.
9. Documents sufficient to show your final written policies for the types of documents or other information and materials provided to TPPs for VCDs dispensed by you.

V. TESTING/INSPECTION

10. Testing (if any) you performed for VCDs, and results thereof.

VI. DISTRIBUTION CENTERS

11. Documents sufficient to identify your distribution centers from which VCDs were shipped, including location and state(s) of locations served by each distribution center.
12. To the extent available, documents sufficient to identify your distribution centers that would have received or shipped VCDs subject to recall.

VII. RECALL

13. Documents sufficient to show the final written policies or procedures specifically governing the VCD recalls, if any.
14. Documents sufficient to show the initial VCD recall communications you received from the Manufacturer Defendant or Wholesaler Defendant from whom you purchased VCDs.
15. Documents sufficient to show the official notice by which you communicated any VCD recall implemented by you to consumers or TPPs.
16. Documents sufficient to identify (by NDC, and by lot and batch information to the extent maintained by you in the ordinary course of business) Recalled VCDs: (a) currently on hand; (b) returned by you; or (c) destroyed by you.
17. Documents sufficient to show a list of your warehouse and/or distribution facilities involved in any VCD recalls.
18. Documents sufficient to show how your retail or other locations of dispensing VCDs de-stock recalled VCDs.

VIII. COMPLIANCE WITH THE DRUG SUPPLY CHAIN SECURITY ACT

19. Documents sufficient to show your final written policies or procedures for the capture and maintenance of the product tracing information for prescription drug transactions pursuant to the Drug Supply Chain Security Act and regulations promulgated thereunder, or internal legacy procedures relating to same prior to the enactment of the DSCSA

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IX. DOCUMENT PRESERVATION

20. Produce the final document/data retention or destruction policies, or sections thereof, pertinent to the documents/data called for by the above requests.

X. INDEMNITY AGREEMENTS

21. Produce all final written indemnity agreements that you have with any VCD supplier from whom you purchased the VCDs at issue in this litigation. You may redact other competitive or sensitive information from the agreement, including information regarding the pricing and volume of your purchases, provided that the indemnity provision is not redacted.

Dated: February , 2020

/s/ Adam Slater

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CERTIFICATE OF SERVICE

I certify that on the day of December, 2019, I electronically transmitted the attached document to counsel of record for all Retail Pharmacy and Wholesaler Defendants.

/s/ Adam M. Slater